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Editorial

NOTES: The next surgical revolution?

The concept of minimally invasive surgery has now become standard practice in all surgical specialties with widespread acceptance. In the field of gastrointestinal surgery, minimally invasive surgery has become synonymous with laparoscopic surgery and this approach has now taken over much traditional open abdominal surgery.

There is considerable interest in pushing the frontiers of minimally invasive surgery and to develop new concepts that will lead to 'ultra-minimally invasive' procedures. One of these concepts has been that of transluminal surgery. Gastroenterologists have been using endoscopes to perform many endoluminal procedures that were once in the realm of a general surgeon. Transluminal surgery is an extension of this approach and allows the practitioner to breach the luminal barrier and access the peritoneal cavity to perform a transluminal procedure. This field has been referred to as Natural Orifice Transluminal Endoscopic Surgery (NOTES), and has been the subject of much professional interest internationally over the last 3 years.

1. The birth of NOTES

The first mention of natural orifice procedures dates back to the 1940s when culdoscopies were performed using an endoscope passed through the recto-uterine pouch to view the pelvic organs. Culdoscopies were taken up by gynaecologists increasingly over the next few decades to perform diagnostic pelvic examinations as well as sterilisation procedures. These should historically be credited as the first natural orifice surgical procedures. Following culdoscopies, transgastric pancreatic necrosectomies were among the very few other natural orifice procedures to develop over the next few decades.

Over the last 3 years, the concept of natural orifice endoscopic procedures has been taken a step further towards performing intra-abdominal diagnostic and therapeutic procedures using more advanced endoscopes and multiple natural orifices. It is the recent uptake of these experimental procedures that has coined the term "NOTES".

The first presentation of a true NOTES procedure was by Drs Reddy and Rao from Hyderabad, India in which they successfully performed transgastric appendicectomies in hens. Although this data were presented in 2002, the first published report of a NOTES procedure was in 2004 by Dr Anthony Kalloo and his team at Johns Hopkins Hospital, where they performed flexible transgastric peritoneoscopy in a porcine survival model. In the same year, Drs Reddy and Rao further invigorated the field by their presentation of a transgastric appendicectomy in a male patient. Although this work still remains unpublished, it is credited as the first human NOTES procedure.

The natural orifice approach to transluminal surgery utilises a flexible endoscope which enters the peritoneal cavity. Endoscopes may be passed via any single or combination of the transgastric, transrectal, transvaginal, and transcystic routes. Each approach has its unique benefits and drawbacks, and as our experience grows, it is likely that some routes will be preferred over others for specific procedures. The peritoneum is usually inflated through the standard endoscope channel. A double channel endoscope is often used to provide the entry points for the necessary instruments in performing the required dissection and retraction.

Since the introduction of NOTES, the medical community has become fascinated by the idea of "scarless" abdominal surgery. A growing volume of international research in animals, and recent limited human studies have confirmed a potential for NOTES procedures, although the exact place of this technology in the patient care algorithms remains unknown. These reports have confirmed the feasibility of a transluminal approach in procedures such as tubal ligation, cholecystectomy, gastrojejunostomy, appendicectomy, nephrectomy, pancreatectomy and splenectomy.

2. NOSCAR

In July 2005, a working group of expert laparoscopic surgeons from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and expert interventional endoscopists representing the American Society for Gastrointestinal Endoscopy (ASGE) came together for a meeting in New York City to address the emerging technology of NOTES. This group identified itself as the Working Group on Natural Orifice Transluminal Endoscopic Surgery and the overriding goal of the meeting was to produce a document that would serve as a guide for the responsible development and application of NOTES. During this meeting, the panel identified challenges and fundamental barriers to clinical application of NOTES (Table 1) and

Table 1 – Technical barriers to NOTES

- Peritoneal cavity access.
- Gastric (intestinal) closure.
- Prevention of infection.
- Development of suturing device/anastomotic (nonsuturing device).
- Spatial orientation.
- Development of a multitasking platform to accomplish procedures.
- Management of iatrogenic intraperitoneal complications and control of hemorrhage.
- Physiologic untoward events and compression syndromes.
- Training in NOTES.

proposed guidelines to the development of this field and its eventual human application. These recommendations were published in a White paper in February 2006 and subsequently re-addressed at the first international conference on NOTES.

Following this pilot meeting, a joint subcommittee was formed by SAGES and ASGE to further assist in the development of this new field, and was named NOSCAR (Natural Orifice Surgery Consortium for Assessment and Research). NOSCAR organized the first international conference on NOTES. This was held in Arizona in March 2006 with approximately 140 physicians attending from 11 different countries. The physicians came together as a team each consisting of at least one gastroenterologist and one surgeon with access to animal lab facilities. The conference participant teams were assigned to separate working groups with the task of developing a detailed roadmap for overcoming the technical barriers that had been identified in the original White Paper. The roadmaps from the working groups were presented the following day and have set an early direction towards building NOTES for the future. The White Paper and presentations from the working groups were made available online at www.noscar.org for individuals interested in the field.

The conference has now become an annual international event dedicated to the progress of NOTES.

It is anticipated that NOSCAR will take on an increasingly important role in coordinating NOTES research for the future within North America as well as internationally, and will link with similar committees that develop elsewhere. NOSCAR will also oversee a NOTES patient registry, as human studies begin. More recently, NOSCAR has been the recipient of several industry awards to fund research in this field, and has taken on the responsibility of processing the competitive grant applications.

3. Advantages of NOTES

Natural orifice surgery remains an experimental procedure, although some believe that this disruptive technology has the potential to significantly alter the care of our surgical patients. It is being introduced as the beginning of ''*the next surgical revolution*'', comparing it to the early days of laparoscopic surgery. The driving force behind this enthusiasm has been the potential advantages of NOTES that include:

(1) Less physiological and immunological insult to the body than laparoscopic or conventional surgery. Current laboratory investigations are underway to study this claim.
(2) The lack of skin and abdominal wounds allows for improved cosmesis and eliminates the potential for wound complications. It is currently debated whether NOTES will result in fewer intra-abdominal adhesions, and this still remains to be proven in large scale studies.
(3) Less post-operative pain and quicker home discharge.
(4) As the procedures are performed entirely endoscopically, there is a general consensus that they may be able to be done without a general anesthesia, and in the endoscopy unit or at the bedside in Intensive Care Settings. This shift of surgical procedure from the OR to another setting is thought to result in cost savings.
(5) Certain groups of patient, in which open or laparoscopic surgery has limitations or challenges (such as the obese), may be particularly suitable for NOTES procedures and benefit the most from it.

Even if NOTES fails to result in a significant change in clinical practice, the technologies that are developed as a result of the current enthusiasm in the field can have uses in other areas. For example, the new endoscopic suturing devices that are currently undergoing clinical evaluation may have a use in closing inadvertent perforations of the GI tract during routine endoscopy, eliminating the need for traditional surgery.

4. Current hurdles to NOTES

The initial concern from most healthcare professionals who first hear about NOTES is the potential for intra-abdominal infection, and leaks from the viscerotomy sites. Although animal studies have shown technical feasibility of closure and safety of this approach, these genuine concerns are real and appropriate. In fact these issues are highlighted in the NOSCAR whitepaper. Currently, there is a lack of a clinically approved viscerotomy closure device on the market, and until the introduction of such a reliable device, the field is unlikely to gain widespread momentum.

NOTES instrumentation continues to be a problem and this remains to be a major hurdle in performing more complex surgery. Instrument optics and triangulation are also major technical barriers and endoscopic instrument manufacturing companies are tackling these challenges through progressive technological advances.

Training in this new field is an area that needs particular attention to help expedite the widespread use of this technique. The development of NOTES on an individual level requires access to training labs, training models, courses, and supervision. The current practice of NOTES represents a truly blended new specialty that blurs the boundaries between gastroenterologists and general surgeons. This is similar to the current practice challenges in endovascular surgery which has successfully developed as a joint effort between interventional radiologists and vascular surgeons. It is much debated as to which specialty will dominate this endoscopic approach in the future, although in reality, both specialties have much

to contribute towards its future progress and development. A demonstration of expertise in flexible endoscopy, visceral anatomy, surgical principles, and managing complications will be expected to the handful of practitioners participating in NOTES.

Hybrid or bridge procedures may provide an initial step towards developing an individual surgeon's practice of NOTES. For example, performing a transluminal peritoneoscopy under traditional laparoscopic vision will allow the practitioner to develop confidence in their transluminal skills and also to perform an external assessment of the security of endoscopic transluminal closure.

5. Summary of human studies

There have been a handful of reported NOTES procedures in humans, with limited breadth and volume. Some well-publicized human reports include:

- Transgastric appendicectomy in 2002 from India.
- Transgastric peritoneoscopy in 2006 from Ohio State University.
- Comparing diagnostic staging laparoscopy for pancreatic cancer versus transgastric peritoneoscopy in 10 patients.
- Transvaginal cholecystectomy with laparoscopic assistance from Columbia University, New York in March 2007.
- Transvaginal cholecystectomy (unassisted) in April 2007 from France (Operation Anubis).
- Transgastric cholecystectomy from Oregon.

There are, however, likely to have been other, less publicized attempts at such procedures. These early and encouraging efforts, as well as reports of limitations from animal studies is helping to further shape and focus the direction that human NOTES procedures will take.

From a different perspective, clinical survey studies have been performed in patient groups to gauge the enthusiasm of our patients about NOTES, and 'scarless' surgery. Results indicate that although not many patients are initially aware of NOTES, upon educating them on the technique, the majority would favour this approach over laparoscopic surgery. Patients are willing to accept NOTES provided a similar or improved procedural risk profile is demonstrable. Interestingly, most patients would also prefer NOTES to be performed via the transoral approach in comparison to the other routes available.

6. Future of NOTES

The current enthusiasm for NOTES is rapidly growing and thus far the concept has shown exciting potential. We must, however, not get carried away with this initial enthusiasm and bypass the appropriate clinical evaluation in a safe and controlled manner.

The future of NOTES applicability rests on the results of studies which will have to demonstrate a clinical superiority from current existing procedures. Risks, costs, and benefits will have to be clearly demonstrated before a widespread uptake can occur amongst the keen practitioners as well as the skeptics.

7. Conclusion

A new era has already begun in minimally invasive surgery, but the question remains as to whether this will revolutionise the field of surgery. Care must be taken in our approach towards accepting this potentially exciting field of therapy. There are noted scientific and technical limitations that must be overcome before a general direction of application can be addressed. One day in the near future, NOTES may become universally accepted and be the preferred choice of treatment by both patients and physicians.

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